UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

SANOFI-AVENTIS U.S., LLC, *Plaintiff*, –v– NORRIS COCHRAN, *et al.*, *Defendants*.	Civil Action No. 3:21-cv-634-FLW-LHG

BRIEF OF AMERICAN HOSPITAL ASSOCIATION, 340B HEALTH, AMERICA'S ESSENTIAL HOSPITALS, ASSOCIATION OF AMERICAN MEDICAL COLLEGES, CHILDREN'S HOSPITAL ASSOCIATION, AND AMERICAN SOCIETY OF HEALTH-SYSTEM PHARMACISTS AS *AMICI CURIAE* IN SUPPORT OF DEFENDANTS

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American Hospital Association, 340B Health, America's Essential Hospitals, Association of American Medical Colleges, National Association of Children's Hospitals d/b/a Children's Hospital Association, and American Society of Health-System Pharmacists, by and through their undersigned attorneys, hereby file this *amicus* brief in support of Defendants' opposition to the cross-motion for summary judgment filed by Plaintiff Sanofi-Aventis U.S., LLC (Sanofi).

Amici are six hospital/health system associations whose members use 340B discounts for 340B drugs dispensed through contract pharmacies to support health care programs and services offered by their hospitals. The discounts, for example, allow these members to (1) provide and maintain more patient care services; (2) provide and maintain more uncompensated and unreimbursed care; (3) provide and maintain more services in underserved areas; (4) develop and maintain targeted programs to serve vulnerable patients; and (5) keep their doors open. Decl. of James W. Boyan III in Supp. of Proposed Intervenors' Mot. to Intervene (Boyan Decl.), Ex. A (Decl. of Maureen Testoni in Supp. of Proposed Intervenors' Mot. to Intervene (Testoni Decl.)) ¶¶ 7–9, ECF No. 34-2.

These discounts are the subject of the Department of Health and Human Services (HHS) General Counsel's Advisory Opinion[1] and a May 17, 2021 letter from the Acting Administrator of the Health Resources and Services Administration (HRSA),[2] that Sanofi challenges, which both concluded that the refusal by drug companies to provide 340B providers 340B discounts for drugs dispensed through contract pharmacies is unlawful, in violation of the 340B statute. *Amici* submit this brief (1) to address Sanofi's argument that the 340B statute does not require drug manufacturers to offer 340B discounts when drugs are dispensed by contract pharmacies; (2) to address Sanofi's argument that the 340B statute allows drug manufacturers to impose whatever conditions they deem reasonable before providing 340B discounts; and (3) to correct Sanofi's misrepresentation of its unlawful policy as merely a benevolent initiative that imposes no burden on 340B providers.

INTRODUCTION

The 340B program, established by section 340B of the Public Health Service Act, 42 U.S.C. § 256b, requires as a condition of participating in Medicaid and

[1] Boyan Decl., Ex. G (*Advisory Opinion 20-06 on Contract Pharmacies Under the 340B Program* (Dec. 30, 2020)).

[2] Letter from Diana Espinosa, Acting Administrator, HRSA, to Gerald Gleeson, VP & Head, Sanofi US Market Access Shared Services, Sanofi (May 17, 2021), https://www.hrsa.gov/sites/default/files/hrsa/opa/pdf/hrsa-letter-sanofi-covered-entities.pdf.

Medicare Part B that pharmaceutical manufacturers sell outpatient drugs at a discounted price to certain public and not-for-profit hospitals, community health centers, and other providers that serve patients with low incomes (340B providers or covered entities). The purpose of the program is to stretch the funding 340B providers have available to meet the needs of their patients. H.R. Rep. No. 102-384(II), at 12 (1992). A 2011 report from the U.S. Government Accountability Office (GAO) found that the 340B program has had this exact effect. Specifically, GAO found that 340B providers have used the benefit made available through the drug discounts to provide critical health care services to communities with underserved populations that could not otherwise afford these services—for instance, by increasing service locations, developing patient education programs, and providing translation and transportation services. GAO, Report to Congressional Committees, GAO-11-836, *Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement* 17–18 (Sept. 2011), https://www.gao.gov/assets/gao-11-836.pdf.

Since the beginning of the program, Sanofi and all other major pharmaceutical companies provided 340B discounts for drugs dispensed through both in-house and contract pharmacies to covered entities' patients, and since 2010 they have sold drugs at the 340B prices to hospitals and other covered entities who used multiple contract pharmacies. For 24 years, between 1996 and July 2020, there is no record

that Sanofi ever contested HHS's interpretation of section 340B as allowing 340B drugs to be dispensed by contract pharmacies. Today, a quarter of the benefit that 340B hospitals receive from the 340B discount comes from 340B drugs dispensed through contract pharmacy arrangements. For some the benefit is even higher, such as critical access hospitals (small hospitals in rural areas) that report that an average of 51% of their benefit from the 340B discount comes from drugs distributed through contract pharmacies. Testoni Decl. ¶ 6. 340B providers use the 340B benefit to provide services to underserved populations in their communities. Recognizing the value of the 340B program, Congress expanded it as part of the 2010 Affordable Care Act. Patient Protection & Affordable Care Act, Pub. L. 111-148, §§ 7101–7103, 124 Stat. 119, 821–28 (2010) (codified at 42 U.S.C. § 256b(a)(4)(M)–(O)).

Although the 340B statute requires discounts to be offered only to statutorily defined covered entities, it does not otherwise limit the size of the program or authorize a pharmaceutical company to do so. The Conference Committee Report accompanying the original enactment stated the HHS Secretary was not authorized to limit in any way the volume of purchases of outpatient drugs by covered entities at the discounted price. H.R. Rep. No. 102–384(II), at 16. Importantly, while the statute requires that the drugs be purchased by a covered entity, it does not limit where the drugs are dispensed. *See* 42 U.S.C. §§ 256b(a)(1), (4).

Nevertheless, starting 11 months ago, in the midst of the most devastating pandemic in 100 years, six major drug companies (which are among the largest companies in an industry that between 2000 and 2018 generated $8.6 trillion dollars in profits[3]) unilaterally and substantially cut the 340B benefit to public and not-for-profit hospitals that serve large numbers of patients with low incomes. Eli Lilly and Co. was the first drug company to abandon its policy of complying with the statute, as interpreted by HHS, and notified HRSA—the HHS division that manages the 340B program—that it would no longer sell drugs at 340B discounted prices if the drugs were dispensed at a contract pharmacy. Five other major drug companies, including Sanofi, soon followed Eli Lilly's lead.[4]

The contract pharmacy arrangements that Sanofi and the other drug companies are refusing to honor have existed since the beginning of the program. When a 340B provider uses a contract pharmacy outside its premises, it enters a written contract. The 340B provider orders and pays for the drugs, which are shipped

[3] Fred D. Ledley et al., *Profitability of Large Pharmaceutical Companies Compared with Other Large Public Companies*, 323(9) J. Am. Med. Ass'n 834–43 (Mar. 3, 2020), https://jamanetwork.com/journals/jama/fullarticle/2762308.

[4] *See* Boyan Decl., Ex. K (Sanofi Notice, July 2020); Boyan Decl., Ex. F (Letter from Odalys Caprisecca, Executive Director, AstraZeneca to 340B Partners, Aug. 17, 2020); Boyan Decl., Ex. L (Novartis Statement, Oct. 30, 2020); Boyan Decl., Ex. M (Memorandum from Kevin Gray, CVP, United Therapeutics Corp. to 340B Covered Entities, Nov. 20, 2020); Boyan Decl., Ex. J (Novo Nordisk Notice, Dec. 1, 2020).

directly to the contract pharmacy to be dispensed to the provider's patients. The pharmacy receives a fee for performing this service.

Under this arrangement, some providers use a separate inventory model, but most use a "replenishment" inventory model. For the separate inventory model, the provider's 340B drugs are kept in stock at the contract pharmacy, separate from non-340B drugs. The contract pharmacy dispenses those drugs to the provider's patients. For the more common "replenishment" model, no 340B drugs are kept in stock. When filling prescriptions for the provider's patients, the contract pharmacy uses drugs from its own stock, and the provider purchases replacement drugs at the discounted price to replenish the pharmacy's stock. The replacement drugs are delivered to the contract pharmacy, which then passes on the payments it received when it dispensed the drugs, less an agreed upon dispensing fee, thus ensuring that the provider receives the benefit of the 340B discount as Congress intended. These arrangements are typically done using a computerized tracking system following rules designed to ensure that only eligible patients of 340B providers are receiving drugs for which the provider receives the 340B discount.[5] Under either arrangement, it is the 340B provider that purchases the 340B discounted drug—not the contract

[5] *See, e.g.*, Apexus, *340B Split-Billing Software Key Attributes* (July 3, 2019), https://www.340bpvp.com/Documents/Public/340B%20Tools/340b-split-billing-software-key-attributes.docx.

pharmacy. Sanofi has ceased providing or restricted provision of 340B discounts for drugs provided under either model.[6]

On December 30, 2020, in an Advisory Opinion issued by its General Counsel (Advisory Opinion), HHS restated its historical position that the refusal by Sanofi and the other drug companies to provide 340B providers 340B discounts for drugs dispensed through contract pharmacies is unlawful. Then on May 17, 2021, HHS sent letters to all six pharmaceutical companies reiterating its position that the drug companies' refusal to provide 340B discounts for drugs dispensed through contract

[6] According to Sanofi, its policy permits "any covered entity that does not have its own in-house pharmacy [to] designate a single contract pharmacy," Second Am. Compl. ¶ 50, ECF No. 78, and it permits covered entities to use unlimited contract pharmacies if they submit to Sanofi "claims data for any 340B-priced prescriptions dispensed by contract pharmacies," *id.* ¶ 46; *see also* Pl.'s Mem. of Law in Supp. of Cross-Mot. for Summ. J. & in Opp'n to Defs.' Mot. to Dismiss or, in the Alternative, for Summ. J. (Pl.'s Br.) 10–11, ECF No. 68-1.

pharmacies is unlawful.[7] Sanofi challenges the Advisory Opinion in its cross-motion for summary judgment, *see* ECF No. 68-1, and both the Advisory Opinion and HHS's letter in its second amended complaint, ¶¶ 131–62 (Advisory Opinion), ¶¶ 163–83 (Letter), ECF No. 78.[8]

[7] Letter from Diana Espinosa, Acting Administrator, HRSA, to Odalys Caprisecca, Executive Director, US Strategic Price & Operations, AstraZeneca Pharmaceuticals LP (May 17, 2021), https://www.hrsa.gov/sites/default/files/hrsa/opa/pdf/hrsa-letter-astrazeneca-covered-entities.pdf; Letter from Diana Espinosa, Acting Administrator, HRSA, to Derek L. Asay, Senior Director, Government Strategy, Eli Lilly & Company (May 17, 2021), https://www.hrsa.gov/sites/default/files/hrsa/opa/pdf/hrsa-letter-eli-lilly-covered-entities.pdf; Letter from Diana Espinosa, Acting Administrator, HRSA, to Dan Lopuch, Managed Market Finance, Novartis Pharmaceuticals Corporation (May 17, 2021), https://www.hrsa.gov/sites/default/files/hrsa/opa/pdf/hrsa-letter-novartis-pharmaceuticals-covered-entities.pdf; Letter from Diana Espinosa, Acting Administrator, HRSA, to Farruq Jafery, VP, Pricing, Contract Operations & Reimbursement, Novo Nordisk, Inc. (May 17, 2021), https://www.hrsa.gov/sites/default/files/hrsa/opa/pdf/hrsa-letter-novo-nordisk-covered-entities.pdf; Letter from Diana Espinosa, Acting Administrator, HRSA, to Gerald Gleeson, VP & Head, Sanofi US Market Access Shared Services, Sanofi (May 17, 2021), https://www.hrsa.gov/sites/default/files/hrsa/opa/pdf/hrsa-letter-sanofi-covered-entities.pdf; Letter from Diana Espinosa, Acting Administrator, HRSA, to Lynn Robson, VP, Associate General Counsel, Market Access, United Therapeutics Corporation (May 17, 2021), https://www.hrsa.gov/sites/default/files/hrsa/opa/pdf/hrsa-letter-united-therapeutics-covered-entities.pdf.

[8] In addition, on December 14, 2020, HHS finalized its proposed Administrative Dispute Resolution regulation. *See* 340B Drug Pricing Program; Administrative Dispute Resolution Regulation, 85 Fed. Reg. 80,632 (Dec. 14, 2020) (codified at 42 C.F.R. pt. 10). Sanofi is also challenging that regulation. *See* Second Am. Compl. ¶¶ 98–130.

DISCUSSION

Sanofi devotes much of its brief to understating the impact of its unlawful policy on 340B providers and overstating how reasonable it is to unilaterally impose conditions found nowhere in the 340B statute on providers. For example, Sanofi claims that "contract pharmacies often keep sizable portions of the discounts that Congress intended for non-profit covered entities and their patients" but cites reports from the Inspector General and the General Accounting Office that provide no support for this assertion. Pl.'s Br. 7 & n.3.[9] More importantly, while Sanofi complains about how some hospitals conduct their business and about how certain arrangements with contract pharmacies function, Sanofi's policy makes no distinction between contract pharmacy arrangements; the conditions of its policy

[9] Even the articles that Sanofi cites published by the Pharmaceutical Research and Manufacturers of America (PhRMA)—which represents pharmaceutical companies and of which Sanofi is a member—do not support Sanofi's claim. *See* Pl.'s Br. 8 n.4 (citing Press Release, PhRMA, *New Analysis Shows Contract Pharmacies Financially Gain From 340B Program With No Clear Benefit to Patients* (Oct. 8, 2020), https://phrma.org/Press-Release/New-Analysis-Shows-Contract-Pharmacies-Financially-Gain-From-340B-Program-With-No-Clear-Benefit-to-Patients; PhRMA, *For-Profit Pharmacies Make Billions Off 340B Program Without Clear Benefit to Patients* (Oct. 7, 2020), https://phrma.org/Graphic/For-Profit-Pharmacies-Make-Billions-Off-340B-Program-Without-Clear-Benefit-to-Patients; PhRMA, Petition for Rulemaking at 5–6 (Nov. 24, 2020) (ADVOP_001383-84)).

apply to ALL arrangements, regardless of the particulars.[10] In order to prevail on its cross-motion for summary judgment, Sanofi would need to show that it is entitled to decline to offer 340B discounts to *all* 340B providers that do *any* business with contract pharmacies. Sanofi has failed to do so.

Sanofi instead attempts to distract from the real issue in this case, which is whether the 340B statute requires drug companies to provide applicable discounts when the drugs are dispensed by a contract pharmacy on behalf of the 340B provider without the drug companies imposing extraneous conditions. For the reasons discussed below, the answer is yes. Thus, even if Sanofi's policy were as benevolent as it suggests—and it is not—Sanofi cannot prevail.

I. The Plain Meaning of the 340B Statute Requires Participating Drug Manufacturers to Give Discounts on 340B Drugs Dispensed by Contract Pharmacies.

"We begin with the text. We look to the statutory provision's language and to the ordinary meaning of the words it uses." *Vorchheimer v. Philadelphian Owners Ass'n*, 903 F.3d 100, 105 (3d Cir. 2018). The 340B statute explicitly requires drug

[10] *E.g.*, Decl. of Jennifer L. Del Medico, Ex. 1 (Sanofi Policy) at 1, ECF No. 68-3 ("Sanofi will require 340B covered entities to submit claims data for 340B prescriptions of Sanofi products filled through its [sic] contract pharmacies. . . . Sanofi is requiring 340B covered entities to register . . . by October 1, 2020."); *id.* at 2 ("Sanofi is requiring 340B covered entities to register . . . and begin providing 340B claims data by October 1, 2020. 340B covered entities that elect not to provide 340B claims data will no longer be eligible to place Bill To / Ship To replenishment orders for Sanofi products dispensed through a contract pharmacy.").

manufacturers to offer 340B discounts to 340B covered entities regardless of whether the drugs are dispensed by the entity or by an outside pharmacy with which the entity has a contract. Specifically, the statute provides that:

> The Secretary shall enter into an agreement with each manufacturer of covered outpatient drugs under which the amount required to be paid . . . to the manufacturers for covered outpatient drugs . . . *purchased by* a covered entity . . . does not exceed an amount equal to the [ceiling price].

42 U.S.C. § 256b(a)(1) (emphasis added). The statute does not say "purchased *and dispensed* by" a covered entity, and the fundamental rule of statutory construction is that, when unambiguous, the plain language of the statute controls, irrespective of the legislative history or other tools of statutory construction. *DirectTV v. Pepe*, 431 F.3d 162, 168 (3d Cir. 2005). "[A]s long as the statutory scheme is coherent and consistent, there generally is no need for a court to inquire beyond the plain language of the statute." *United States v. Ron Pair Enters., Inc.*, 489 U.S. 235, 240–41 (1989). Thus, contrary to Sanofi's assertion otherwise, Pl.'s Br. 24–30, the 340B statute's plain language does require manufacturers to provide discounts for drugs purchased by 340B providers regardless of whether they are dispensed by contract pharmacies.

In fact, an earlier version of the bill that was not enacted did address how or where the 340B drug must be dispensed. That unenacted version stated that 340B discounts would be required for drugs "purchased *and dispensed by, or under a contract entered into for on-site pharmacy services with*" a covered entity. S. Rep.

No. 102-259, at 2 (1992) (emphasis added). If that language had been retained, the 340B discounts would have been allowed *only* for on-site pharmacy services, since the drugs would have had to have been "purchased and dispensed by, or under a contract entered into *for on-site pharmacy services*." *Id.* (emphasis added). The elimination of the phrases "dispensed by" and "on-site pharmacy services" changed the provision to render where the 340B drug is dispensed legally irrelevant—all that matters is that the drug be "purchased by a covered entity." 42 U.S.C. § 256b(a)(1). It is not surprising that Congress decided to drop the additional language and permit dispensing by a contract pharmacy because, at the time the bill was passed, less than 5% of 340B providers had on-site dispensing services. *See* Notice Regarding Section 602 of the Veteran Health Care Act of 1992; Contract Pharmacy Services, 61 Fed. Reg. 43,549, 43,550 (Aug. 23, 1996).

Sanofi cites this same unenacted language as evidence that Congress "declined to require 340B pricing for prescriptions dispensed by on-site contract pharmacies" and so could not have intended to require 340B discounts for 340B drugs dispensed by off-site contract pharmacies. Pl.'s Br. 29. Sanofi's argument ignores that Congress also eliminated the "dispensed by" language, meaning that the 340B statute, as enacted, does *not* limit the requirement on drug manufacturers to offer 340B discounts to drugs *dispensed by* the covered entity itself. Indeed, had Congress intended for the 340B program to be as limited as Sanofi suggests (*i.e.*, no

340B discounts required unless the drugs are dispensed directly by the covered entity, excluding the use of even in-house pharmacies with which the covered entity has contracted to dispense its drugs), it would have said so explicitly, either in 1992 when originally enacting the statute or in 2010 when it amended the statute, and it would not have *rejected* language in 1992 doing just that.

Sanofi's principal statutory argument is that a requirement to provide 340B discounts even if drugs are dispensed using contract pharmacies is inconsistent with the statute because contract pharmacies are not listed as covered entities, but this argument merely sidesteps the real issue. *See id.* at 24–26. Sanofi is correct that a contract pharmacy is not a covered entity under the 340B statute, but that argument is irrelevant and neither HHS nor *amici* have ever argued otherwise. The 340B drugs are *not* being sold (or offered) to the contract pharmacies; they are being sold to 340B hospitals and other covered entities. That is what the statute requires. The statute does not dictate how or where 340B drugs must be dispensed to a covered entity's patients.

Sanofi also wrongly argues that HHS's reference to contract pharmacies as covered entities' "agents" has no basis in the statute and that Congress made "a deliberate choice" in not including agents of covered entities within the statutory scheme. *Id.* at 26–28. The nomenclature used to characterize the relationship between a covered entity and a contract pharmacy is irrelevant so long as the

statutory requirement that the drug is "purchased by a covered entity" for its patients is met. Sanofi's reference to another provision in the statute that addresses "agents acting on behalf of covered entities," *id.* at 27, also does not support its claim that Congress would have expressly referenced contract pharmacies if it had meant them to be part of the statutory scheme. That provision, as well as the other examples of statutory provisions Sanofi provides, is inapposite. The reason the statute specifically provides at section (d)(3)(B)(vi) that associations or organizations that represent the interests of covered entities can bring claims on the covered entities' behalf through the Administrative Dispute Resolution (ADR) process is because without it, associations could not bring claims at all because they are not covered entities. Similarly, the reason the statute at section (d)(1)(B)(v) references wholesalers as being subject to auditing is because without that reference, the wholesalers would not be subject to auditing, because they are not drug manufacturers. For the same reason, Congress referenced distributors in section (d)(2)(B)(iv) because they, like manufacturers, need to be able to identify covered entities.[11]

The fact that Congress referenced entities other than drug manufacturers and covered entities in three places in the statute is irrelevant to whether the statute

[11] Sanofi mistakenly describes these provisions as applying to distributors and wholesalers acting on behalf of covered entities, rather than on behalf of manufacturers. Pl.'s Br. 27.

requires drug manufacturers to provide 340B discounts for drugs dispensed by contract pharmacies. Likewise, the absence of references to contract pharmacies in the statute is irrelevant because contract pharmacies are not purchasing the 340B drugs, and a covered entity's entitlement to the 340B discount does not depend on how or where the drug is dispensed to its patients. Similarly, contrary to Sanofi's argument, Pl.'s Br. 27, there was no need for Congress to include language in the 340B statute referring to contract pharmacies the way it referenced contracts in 38 U.S.C. § 8126(h)(3)(A), an unrelated statute involving contracts between commercial entities and certain federal agencies.

Sanofi next argues that "Section 340B's only requirement of manufacturers is that they 'offer' discounted drugs to covered entities," and that the statute "separately requires the Secretary to enter into [agreements] addressing what manufacturers should be paid for drugs 'purchased by' a covered entity, but that requirement imposes no obligations on manufacturers." Pl.'s Br. 29–30 (quoting 42 U.S.C. § 256b(a)(1)). This argument does not survive a reading of the statute. While the sentence with the "purchased by" language directs the Secretary to enter into an agreement with the drug manufacturer, it also describes what that

agreement—to which the manufacturer is a party—requires. For Sanofi to argue that the language does not apply to manufacturers is beyond comprehension.[12]

Moreover, the "must offer" language, even if read in isolation, does not support Sanofi's argument. That provision states that the agreement entered into by the Secretary "*shall require* that the manufacturer *offer* each covered entity covered outpatient drugs *for purchase* at or below the applicable ceiling price if such drug is made available to any other purchaser at any price." 42 U.S.C. § 256b(a)(1) (emphasis added). This language addresses the price at which the drug must be offered (no higher than the best price available), but it does not condition that offer on whether the drug is dispensed on the covered entity's premises.

Finally, Sanofi misrepresents the Advisory Opinion as "rel[ying] on principles of state agency law to insist that a drug is 'purchased by' a covered entity when the prescription is filled at a contract pharmacy and provided to a patient." Pl.'s Br. 30 (citing Advisory Opinion 6). No reliance on principles of state agency law is required here: the *covered entity purchases* the 340B drug and the *contract pharmacy dispenses* the drug to the covered entity's patient. The Advisory Opinion does not suggest that in order for drug manufacturers to be required to offer drugs at 340B

[12] This argument also makes no sense because the "offer" language, which Sanofi claims is the only part of the statute that imposes an obligation on manufacturers, was not added to the statute until 2010, meaning that under Sanofi's argument the statute would have placed no obligation on manufacturers to provide *any* 340B discounts prior to 2010.

discounts there needs to be a state-by-state, contract-by-contract analysis of whether a common-law agency relationship exists between the covered entity and the contract pharmacy. Rather, the Advisory Opinion rebuts the drug manufacturers' argument—which Sanofi alludes to in its brief, *see id.* at 29 & n.12—that by allowing 340B drugs to be dispensed by contract pharmacies, covered entities are engaging in unlawful drug diversion, *see* 42 U.S.C. § 256b(a)(5)(B).

The Advisory Opinion thus merely explains that the covered entity and contract pharmacy "function as principal-agent," Advisory Opinion 6, insofar as the pharmacy acts on the covered entity's behalf by dispensing its prescriptions to its patients. It is not unusual for the terms "agency" or "agent" to be used without meaning to invoke the common-law definition. As explained in the Restatement (Third) of Agency, "[s]ome statutes and many cases use agency terminology when the underlying relationship falls outside the common-law definition. Moreover, the terminology of agency is widely used in commercial settings and academic literature to characterize relationships that are not necessarily encompassed by the legal definition of agency." Restatement (Third) of Agency § 1.01 cmt. (2006).

II. The 340B Statute Does Not Allow Sanofi to Impose Conditions It Deems Reasonable on Covered Entities.

Drug manufacturers may not add requirements to the 340B statute. Sanofi argues that because the 340B statute requires only that drug manufacturers "must offer" 340B discounts on 340B drugs to covered entities and does not define "offer,"

Sanofi may impose whatever conditions it unilaterally deems "reasonable" upon covered entities. Pl.'s Br. 30–33. Sanofi cites no authority for its contention that, where a statute requires a private entity to act in a certain manner, the private entity may unilaterally impose additional conditions on that requirement.

Sanofi instead identifies only HHS's 1994 guidance, which "advised that manufacturers may condition an offer of 340B-priced drugs on a covered entity's provision of 'standard information.'" *Id.* at 32 (quoting Final Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Entity Guidelines, 59 Fed. Reg. 25,110, 25,114 (May 13, 1994)). But Sanofi fails to mention that in that very guidance HHS plainly stated that "[m]anufacturers may not single out covered entities from their other customers for restrictive conditions that would undermine the statutory objective," 59 Fed. Reg. at 25,112; that "[m]anufacturers must not place limitations on the transactions (e.g., minimum purchase amounts) which would have the effect of discouraging entities from participating in the discount program," *id.* at 25,1113; and that "[a] manufacturer may *not* condition the offer of statutory discounts upon an entity's assurance of compliance with section 340B provisions," *id.* (emphasis added). Directly relevant to this case, HHS specifically stated that

> [c]overed entity assurances regarding the following activities may not be required: . . . (2) utilization of covered outpatient drugs only in authorized services; . . . (4) permitting the manufacturers to audit purchase, inventory, and related records prior to the publication of approved [340B] guidelines; and (5)

> submitting information related to drug acquisition, purchase, and inventory systems.

Id. at 25,113–14; *see also* 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation, 82 Fed. Reg. 1,210, 1,223 (Jan. 5, 2017) ("Manufacturers cannot condition the sale of a 340B drug at the 340B ceiling price because they have concerns or specific evidence of possible non-compliance by a covered entity"). The conditions Sanofi's policy imposes on 340B providers are thus plainly disallowed and are certainly not equivalent to conditions that, for example, allow for manufacturers to operate in accordance with "normal business policies." Pl.'s Br. 32 (quoting 59 Fed. Reg. at 25,112).

HHS has recognized in its guidances that Congress intended for the 340B program to function in the real world, meaning that certain conditions, such as complying with standard business practices, may be necessary to fulfill statutory obligations. But Sanofi identifies nothing in the statute or otherwise that demonstrates Congress's intent to allow drug manufacturers to impose whatever other conditions they independently deem "reasonable." If Sanofi's interpretation of the statute were correct, it could impose essentially whatever conditions it desired upon covered entities, defying Congress's intent in enacting the 340B program. For example, Sanofi could require that all covered entities provide the data it seeks regardless of how they dispense 340B drugs; it could require that covered entities dispense 340B drugs using only certain retail pharmacies; or it could impose

minimum purchase requirements (which HHS specifically exemplified as an impermissible condition, 59 Fed. Reg. at 25,113). Drug manufacturers could present any of these conditions as "reasonable," but the statute does not allow for manufacturers to impose them.

Underlining this point is the fact that Sanofi's conditions, which Sanofi insists "impose[] no logistical or financial burden on covered entities," Pl.'s Br. 33, do add to the workload of hospitals that continue to deal with the unprecedented challenges of the pandemic.[13] For one, Sanofi's policy "requires claims uploads every two weeks." Sanofi Policy 2. Covered entities are required to register for, work with, and comply with the terms of a third-party platform. *See id.*; https://340besp.com/.[14] And hospitals are responsible for ensuring that the release of any claims data is in

[13] Sanofi incorrectly asserts that none of the covered entity associations that are joining this brief as *amici* have argued that the demand for claims data would be burdensome. Pl.'s Br. 12. This is not true, and for example, as early as August 11, 2020, one of the *amici* wrote to Sanofi to express its serious concerns about the overly broad scope of Sanofi's demand for contract pharmacy claims data, the legal issues raised by the demand, and the burdens that it would place on safety net hospitals during the COVID-19 pandemic. *See* Letter from Maureen Testoni, President and CEO, 340B Health, to Gerald Gleeson, VP & Head, Sanofi US Market Access Shared Services, Sanofi-Aventis, U.S. LLC (Aug. 11, 2020), https://www.340bhealth.org/files/340B_Health_Letter_on_Sanofis_Requests_for_340B_Claims_Data_8.11.2020.pdf.

[14] In this instance, the platform is operated by Aaron Vandervelde, a long-time advocate for limiting the 340B program who has moved for leave to file an *amicus* brief in this action. *See* https://340besp.com/about.

compliance with state and federal requirements. This places additional personnel and financial burdens on hospitals that are not authorized by the statute.

Additionally, Sanofi maintains that it enacted its unlawful policy and is imposing conditions on 340B providers out of a desire "to identify and halt impermissible duplicate discounts," Second Am. Compl. ¶ 47, but Congress did not give drug manufacturers the authority to unilaterally halt providing discounts to covered entities for this reason. Rather, Congress provided them and HHS with the authority to address suspected duplicate discounts through audits. 42 U.S.C. §§ 256b(a)(5), (d)(2). If after an audit and a hearing, the HHS Secretary (not the manufacturer) finds that the covered entity has violated the prohibition on diversion or duplicate discounts, the covered entity must pay a refund to the manufacturer. *Id.*; *see also* Manufacturer Audit Guidelines and Dispute Resolution Process 0905-ZA-19, 61 Fed. Reg. 65,406 (Dec. 12, 1996) (establishing guidelines for audits, as required by section 256(a)(5)(C)). Congress therefore clearly considered the risk of duplicate discounts in the 340B program and specifically addressed them; in order to protect 340B providers from the potentially onerous burdens that giving unlimited audit authority to manufacturers would have permitted, Congress specifically required that audits only be done in accordance with guidance from HHS regarding the number, duration, and scope of the audits. *Cf. Fin. Planning Ass'n v. S.E.C.*, 482 F.3d 481, 488 (D.C. Cir. 2007) (agency not allowed to broaden statutory exemptions

where "legislative 'intent' does not support an exemption . . . broader than the exemption set forth in the text of [the statute]" and where Congress "already expressly addressed" the issue in another provision of the statute); *id.* at 490 (finding statutory scheme inconsistent with interpretation that gives agency authority to expand provision's coverage). Sanofi identifies no authority that would allow for a different conclusion.

Although not relevant to whether the statute allows it to attempt to unilaterally address duplicate discounting concerns—it does not—Sanofi repeatedly claims that duplicate discounting is a rampant problem that no one is addressing. Sanofi maintains without support that "[d]uplicate discounting has . . . spiked as the use of contract pharmacies has exploded in recent years—with HHS unfortunately having done nothing about it." Pl.'s Br. 1–2 (citing no authority); *see also id.* at 8 (claiming, without citation, that "the expansion of contract pharmacy arrangements has led to widespread duplicate discounting"); *id.* at 9 & n.9 (characterizing HRSA audits as having found "widespread duplicate discounting at contract pharmacies" when the audit findings included covered entities that were found to *potentially* have duplicate discount issues, without indicating whether any duplicate discounts occurred with drugs dispensed at a contract pharmacies, and in many cases noting that it was later determined that duplicate discounts had not in fact occurred, *see* https://www.hrsa.gov/opa/program-integrity/audit-results/fy-19-results); *id.* at 38 &

n.15 (same). In fact, the most recent GAO report addressing this issue indicated that between 2012 and 2019, *only 23* of the 429 duplicate discount findings related to contract pharmacies. GAO, HHS Uses Multiple Mechanisms to Help Ensure Compliance with 340B Requirements, GAO-21-107, at 14 (Table 1) (Dec. 2020), https://www.gao.gov/assets/gao-21-107.pdf.

Finally, Sanofi portrays its data demands as an "integrity initiative" by which it "can identify and halt impermissible duplicate discounts . . . by comparing the claims data to Medicaid payor data," Pl.'s Br. 10, 11, but the data Sanofi requires from covered entities go far beyond what could potentially address Medicaid duplicate discounts. Sanofi is not just requesting Medicaid claims data; it is demanding from providers *all* contract pharmacy claims data for Sanofi's products, including Medicare Part D and commercial claims. *See* Sanofi Policy. Neither the 340B statute nor any other federal law requires covered entities to take steps to prevent manufacturers from providing 340B discounts on Medicare Part D claims, nor does any federal law require covered entities to help a manufacturer avoid providing for the same drug both a 340B discount and a commercial rebate that the manufacturer voluntarily has offered under agreements with pharmacy benefit managers.

III. The Advisory Opinion Reiterates HHS's Longstanding Policy on Contract Pharmacies.

Sanofi contends that the Advisory Opinion "fails to acknowledge that HHS changed positions on contract pharmacies," Pl.'s Br. 39, but it is Sanofi that fails to acknowledge that HHS's position has been consistent for at least ten years since in 2010 it expressly allowed covered entities to use more than one contract pharmacy. Since the inception of the 340B program, HHS has repeatedly recognized the statutory requirement to offer 340B providers covered drugs at or below 340B ceiling prices when they are dispensed by a contract pharmacy. As detailed below, these statements have been consistent and comprehensive, and they demonstrate that HHS has never wavered in its interpretation of the statute. Sanofi's claim to the contrary is erroneous.

In 1996, HRSA issued "final guidelines" specifically addressing the use of contract pharmacies. Those guidelines recalled that since the beginning of the 340B program, HHS had recognized that 340B providers were permitted to use contract pharmacies to dispense 340B drugs, so long as they complied with the prohibition on drug diversion. 61 Fed. Reg. at 43,550 ("As early as 1993, several covered entity groups . . . came forward to assist the Department in developing a workable mechanism to use outside pharmacies. . . ."). At the same time, HRSA noted that "[t]here is no requirement for a covered entity to purchase drugs directly from the manufacturer or to dispense drugs itself" and that "[i]t is clear that Congress

envisioned that various types of drug delivery systems would be used to meet the needs of the very diversified group of 340B covered entities." *Id.* at 43,549.

HRSA also recognized that "[a]s a matter of State law, entities possess the right to hire retail pharmacies to act as their agents in providing pharmaceutical care to their patients" and that "even in the absence of Federal guidelines, covered entities have the right to contract with retail pharmacies for the purpose of dispensing 340B drugs." *Id.* at 43,550. HRSA agreed with commenters that "[b]y issuing guidelines [the Office of Drug Policy, a Division of HRSA, was] not seeking to create a new right but rather [was] simply recognizing an existing right that covered entities enjoy under State law." *Id*. Finally, HRSA stated that "[u]nder section 340B, . . . *if a covered entity using contract pharmacy services requests to purchase a covered drug from a participating manufacturer, the statute directs the manufacturer to sell the drug at the discounted price*." *Id.* at 43,555 (emphasis added). In 2010, HRSA again acknowledged that "[u]nder section 340B, if a covered entity using contract pharmacy services requests to purchase a covered outpatient drug from a participating manufacturer *the statute directs the manufacturer to sell the drug at a price not to exceed the statutory 340B discount price*." Notice Regarding 340B Drug Pricing Program—Contract Pharmacy Services, 75 Fed. Reg. 10,272, 10,278 (Mar. 5, 2010) (emphasis added). The 2020 Advisory Opinion and HRSA's recent letter to Sanofi restate this longstanding position.

Sanofi contends that the government's claims that it has consistently applied the contract pharmacy policy described in the Advisory Opinion since its first guidance was issued in 1996 cannot be accurate. Sanofi relies on its observation that the Advisory Opinion relies on the "must offer" language in section 340B(a)(1), which was added to the statute after the 1996 and 2010 guidance documents were issued. Pl.'s Br. 39–40. The critical flaw in this claim is that in addition to "must offer," the Advisory Opinion relies on the phrase "purchased by," the original 1992 language in the first sentence of subsection (a)(1) of the 340B statute. This is the same language HHS relied on at the beginning of both the 1996 and 2010 Federal Register notices. *See* Advisory Opinion at 2–3.

And contrary to Sanofi's argument otherwise, it is irrelevant that HHS repeatedly stated that its guidance is not binding and that its authority to enforce 340B guidances is limited. *See* Pl.'s Br. 46–47. Though they have value in informing regulated industry of the agency's thinking and of its interpretation of the statute, guidances are never binding and cannot by themselves be enforced. The statute, however, *is* binding, and here the statute requires manufacturers to sell 340B drugs at discounted prices to providers that contract to have the drugs they prescribe

dispensed to their patients at pharmacies not on their premises. The guidances correctly interpreted the statute.[15]

Sanofi further argues that HHS's current position departs from the 1996 and 2010 guidances because it does not limit the number of contract pharmacies a 340B provider can use and because the 1996 and 2010 guidances are "inconsistent." Pl.'s Br. 47–48. While *Amici* question whether HHS had the authority to impose such a limitation, it is significant that 340B providers never challenged the 1996 guidance's limitation to only one contract pharmacy. Moreover, as discussed above, HHS corrected any such error in 2010 when it eliminated any limitation on the use of contract pharmacies, as required by the plain language of the statute, which is

[15] Also irrelevant (and incorrect) is Sanofi's claim that a recent GAO report noted that HRSA had stopped auditing contract pharmacies for diversion because the 340B statute does not specifically mention contract pharmacies. Pl.'s Br. 46–47 (citing GAO, *HHS Uses Multiple Mechanisms to Help Ensure Compliance with 340B Requirements*, GAO-21-107 (Dec. 2020), https://www.gao.gov/assets/gao-21-107.pdf (2020 GAO Report)). Sanofi misrepresents what the report actually stated. The relevant portion of the report concerned providers' obligation to conduct internal audits of contract pharmacies. *See* 2020 GAO Report 15–16. As the audit findings posted on HRSA's website show, HRSA is still issuing audit findings for diversion related to contract pharmacies. *E.g.*, HRSA, Program Integrity: FY20 Audit Results, HRSA (updated May 19, 2021), https://www.hrsa.gov/opa/program-integrity/audit-results/fy-20-results.

controlling.[16] The important thing is that the 1996 and 2010 guidances, like the Advisory Opinion and the May 17 letter, provided that if a covered entity using contract pharmacy services requests to purchase a covered drug from a participating manufacturer, the statute directs the manufacturer to sell the drug at the discounted price.

CONCLUSION

Sanofi's refusal to offer 340B drugs at discounted prices when dispensed through contract pharmacies (unless the 340B provider complies with Sanofi's demands for data) is at odds with the 340B statute and with HHS's longstanding interpretation of the statute and, worse, jeopardizes 340B hospitals' ability to care for patients during the most serious public health crisis in the last century. For the reasons set forth above, this Court should uphold HHS's correct interpretation of the statute and deny Sanofi's cross-motion for summary judgment.

[16] Sanofi's emphasis that the 2010 guidance merely "*permitted* covered entities to use an unlimited number of contract pharmacies," Pl.'s Br. 47 (emphasis in original), is confusing, as HHS does not now *require* covered entities to use an unlimited number of contract pharmacies, and HHS's position is plainly consistent with the 2010 guidance, which *permitted* covered entities to use unlimited contract pharmacies and thus expected drug manufacturers to comply with their statutory obligation to continue providing 340B discounts regardless of the number of contract pharmacies used.

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Respectfully submitted,

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